

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

EXELIXIS, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 19-2017-RGA-SRF
)	
MSN LABORATORIES PRIVATE LIMITED)	
and MSN PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

**MSN LABORATORIES PRIVATE LTD. AND MSN PHARMACEUTICALS INC.’S
FIRST AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendants MSN Laboratories Private Ltd. (“MSN Laboratories”) and MSN Pharmaceuticals Inc. (“MSN Pharmaceuticals”) (collectively, “MSN”), by and through the undersigned attorneys, respond to Exelixis, Inc.’s (“Exelixis” or “Plaintiff”) Complaint for Patent Infringement as follows:

Pursuant to Fed. R. Civ. P. 8(b)(3), MSN denies all allegations in Plaintiff’s complaint, except those expressly admitted below.

1. MSN admits that Plaintiff’s Complaint against MSN is for infringement of United States Patent Nos. 7,579,473 (the “’473 patent”) and 8,497,284 (the “’284 patent”) arising under the Patent Laws of the United States, 35 U.S.C. § § 100 as well as the Declaratory Judgment Act, 28 U.S.C. §§2201-02, but denies that Plaintiff is entitled to any such relief. MSN further admits that it submitted an Abbreviated New Drug Application (“ANDA”) No. 213878 seeking U.S. Food and Drug Administration (“FDA”) approval to market a generic cabozantinib product, which Plaintiff markets as a product called CABOMETYX[®], prior to the expiration of the ’473 and ’284 patents. MSN denies any remaining allegations in paragraph 1.

PARTIES

2. On information and belief, MSN admits Exelixis's state of incorporation and business address. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 2, and therefore, denies those allegations.

3. MSN admits that MSN Laboratories Private Limited ("MSN Laboratories") is a Private Limited company organized and existing under the laws of India, with a principal place of business at MSN House, Plot No.: C-24, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, India, 500018.

4. MSN admits that MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") is a corporation organized and existing under the laws of Delaware, with a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSN admits that MSN Pharmaceuticals is a wholly owned subsidiary of MSN Laboratories.

5. MSN admits that MSN Laboratories is in the business of developing and manufacturing pharmaceutical products for distribution throughout the United States. MSN denies any remaining allegations of paragraph 5.

6. MSN admits that MSN Pharmaceuticals is in the business of importing and distributing pharmaceutical products for sale and use throughout the United States. MSN denies any remaining allegations of paragraph 6.

7. MSN admits the allegations contained in paragraph 7.

8. Paragraph 8 contains conclusions of law for which no response is required. To the extent a response is required, MSN states that MSN Pharmaceuticals is the U.S. Agent for MSN Laboratories. MSN denies any remaining allegations contained in paragraph 8.

9. MSN admits that it seeks FDA approval of ANDA No. 213878. MSN further admits that it intends to offer to sell and/or sell MSN's ANDA product that is the subject of ANDA

No. 213878 throughout the United States. MSN denies any remaining allegations contained in paragraph 9.

JURISDICTION AND VENUE

10. Paragraph 10 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that this action cites the patent laws of the United States generally. MSN does not contest that this Court has jurisdiction over the subject matter of this action against MSN for the purposes of the asserted patents in this action only.

11. Paragraph 11 contains conclusions of law for which no response is required. To the extent a response is required, MSN does not contest that this Court has personal jurisdiction for the purposes of this action only. MSN admits that it intends to offer to sell and/or sell MSN's ANDA product that is the subject of ANDA No. 213878 throughout the United States. MSN denies any remaining allegations contained in paragraph 11.

12. Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, MSN does not contest that this Court has personal jurisdiction for the purposes of this action only. MSN admits that it intends to offer to sell and/or sell MSN's ANDA product that is the subject of ANDA No. 213878 throughout the United States. MSN denies any remaining allegations contained in paragraph 12.

13. Paragraph 13 contains conclusions of law for which no response is required. To the extent a response is required, MSN does not contest that this Court has personal jurisdiction for the purposes of this action only. MSN admits that MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware, with a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSN denies any remaining allegations contained in paragraph 13.

14. Paragraph 14 contains conclusions of law for which no response is required. To the extent a response is required, MSN does not contest that this Court has personal jurisdiction for the purposes of this action only.

15. MSN admits that it has previously filed counterclaims in this forum. MSN denies any remaining allegations contained in paragraph 15.

16. Paragraph 16 contains conclusions of law for which no response is required. To the extent a response is required, MSN does not contest venue for the purposes of this action only. MSN admits that MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware. MSN denies any remaining allegations contained in paragraph 16.

17. Paragraph 17 contains conclusions of law for which no response is required. To the extent a response is required, MSN does not contest venue for the purposes of this action only. MSN admits that MSN Laboratories is not a resident of the United States. MSN denies any remaining allegations contained in paragraph 17.

BACKGROUND

18. MSN admits that the USPTO issued the '473 patent entitled "C-Met Modulators and Methods of Use" on August 25, 2009, but specifically denies the patent was duly and legally issued. MSN admits that the USPTO's assignment database lists Exelixis as the assignee of the '473 patent. MSN admits that a purported copy of the '473 patent was attached to Exelixis's Complaint as Exhibit A. MSN admits that the USPTO issued the '284 patent entitled "C-Met Modulators and Methods of Use" on July 30, 2013, but specifically denies the patent was duly and legally issued. MSN admits that the USPTO's assignment database lists Exelixis as the assignee of the '284 patent. MSN admits that a purported copy of the '284 patent was attached to Exelixis's Complaint as Exhibit B. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 18, and therefore, denies those allegations.

19. MSN admits that the FDA's Orange Book states that New Drug Application No. 208692 covers CABOMETYX®, and the CABOMETYX® label further indicates that CABOMETYX® (cabozantinib) is a tyrosine kinase inhibitor, for oral administration, for the treatment of patients with advanced kidney cancer (renal cell carcinoma) and patients with liver cancer (hepatocellular carcinoma) who have been previously treated with the medicine sorafenib. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 19, and therefore, denies those allegations.

20. MSN admits that, as of the date of this Answer, the '473 and '284 patents are listed in the FDA's Orange Book in connection with CABOMETYX®. MSN denies any remaining allegations contained in paragraph 20.

21. MSN admits to having sent a Notice Letter dated May 4, 2020. MSN states the letter speaks for itself and no further answer is required. To the extent a response is required, MSN admits that it submitted ANDA No. 213878 to the FDA for generic cabozantinib s-malate tablets, 20 mg, 40 mg, and 60 mg. MSN denies any remaining allegations contained in paragraph 21.

22. Paragraph 22 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits that the MSN ANDA product is bioequivalent to CABOMETYX®. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 22, and therefore, denies those allegations.

23. MSN admits to having sent a Notice Letter dated May 4, 2020. MSN states the letter speaks for itself and no further answer is required. To the extent a response is required, MSN admits that its ANDA included a paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the '473 and '284 patents and alleged that the '473 and '284 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or

sale of the MSN ANDA Product. MSN denies any remaining allegations contained in paragraph 23.

24. MSN admits that ANDA No. 213878 contains a Paragraph IV certification for the '473 and '284 patents. MSN denies any remaining allegations contained in paragraph 24.

25. MSN lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 25, and therefore, denies those allegations.

26. Paragraph 26 contains conclusions of law for which no response is required. To the extent a response is required, MSN states that it does not intend to contest the timeliness of the filing of this complaint upon receipt of MSN's Notice Letter.

CLAIMS FOR RELIEF
COUNT I: INFRINGEMENT OF US PATENT NO. 7,579,473

27. MSN incorporates its responses to each of the preceding paragraphs 1-26 as if fully set forth herein.

28. MSN admits to having sent a Notice Letter dated May 4, 2020. MSN states the letter speaks for itself and no further answer is required. To the extent a response is required, MSN denies any remaining allegations contained in paragraph 28.

29. MSN admits that the filing of its ANDA with a Paragraph IV certification constitutes an artificial act of infringement under 35 U.S.C. § 271(e)(2)(A). MSN denies any remaining allegations contained in paragraph 29.

30. MSN denies the allegations contained in paragraph 30.

31. MSN denies the allegations contained in paragraph 31.

32. Paragraph 32 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits the allegations of this paragraph.

33. MSN denies the allegations contained in paragraph 33.

34. MSN denies the allegations contained in paragraph 34.

35. MSN denies the allegations contained in paragraph 35.

COUNT II: INFRINGEMENT OF US PATENT NO. 8,497,284

36. MSN incorporates its responses to each of the preceding paragraphs 1-26 as if fully set forth herein.

37. MSN admits to having sent a Notice Letter dated May 4, 2020. MSN states the letter speaks for itself and no further answer is required. To the extent a response is required, MSN denies any remaining allegations contained in paragraph 37.

38. MSN admits that the filing of its ANDA with a Paragraph IV certification constitutes an artificial act of infringement under 35 U.S.C. § 271(e)(2)(A). MSN denies any remaining allegations contained in paragraph 38.

39. MSN denies the allegations contained in paragraph 39.

40. MSN denies the allegations contained in paragraph 40.

41. MSN denies the allegations contained in paragraph 41.

42. MSN denies the allegations contained in paragraph 42.

43. Paragraph 43 contains conclusions of law for which no response is required. To the extent a response is required, MSN admits the allegations of this paragraph.

44. MSN denies the allegations contained in paragraph 44.

45. MSN denies the allegations contained in paragraph 45.

46. MSN denies the allegations contained in paragraph 46.

PRAYER FOR RELIEF

MSN denies that Exelixis is entitled to any of the relief requested in its Prayer for Relief or to any relief whatsoever, including those specifically requested as against MSN.

MSN'S AFFIRMATIVE DEFENSES

Further answering the Complaint, MSN asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. MSN reserves the right to amend this Answer with additional defenses as further information is obtained in discovery. MSN asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE **(Invalidity)**

The '473 and '284 patents and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE **(Obviousness-Type Double Patenting)**

The '473 and '284 patents and each of the claims thereof are invalid for obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE **(No Direct Infringement)**

MSN does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '473 and '284 patents. If the product that is the subject of ANDA No. 213878 were marketed, MSN would not infringe any valid and enforceable claim of the '473 and '284 patents.

FOURTH AFFIRMATIVE DEFENSE **(No Indirect Infringement)**

MSN has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '473 and '284 patents. If the product that

is the subject of ANDA No. 213878 were marketed, MSN would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '473 and '284 patents.

FIFTH AFFIRMATIVE DEFENSE
(Prosecution History Estoppel)

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '473 and '284 patents, Plaintiff is estopped from maintaining that any valid or enforceable claims of the '473 and '284 patents are infringed by the product that is the subject of MSN's ANDA No. 213878.

SIXTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim for relief against MSN.

SEVENTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

The Complaint fails to state a claim for relief against MSN for an exceptional case under 35 U.S.C. § 285.

EIGHTH AFFIRMATIVE DEFENSE
(No Willful Infringement)

MSN has not willfully infringed any claim of the '473 and '284 patents.

NINTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Defendant MSN respectfully requests that Plaintiff takes nothing by way of its Complaint, that judgment be entered in favor of MSN, that MSN be awarded its attorneys' fees and costs, and all other just and proper relief.

**MSN LABORATORIES PRIVATE LTD. AND MSN PHARMACEUTICALS INC.'S
FIRST AMENDED COUNTERCLAIMS FOR DECLARATORY JUDGMENT**

For their first amended counterclaim against Exelixis, Inc. (“Exelixis”), Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc. (“Counterclaim Plaintiffs” or “MSN”) state as follows:

THE PARTIES

1. MSN Laboratories Private Ltd. (“MSN Laboratories”) is a company organized and existing under the laws of India, having a principal place of business at Plot #C-24, Industrial Estate, Sanathnagar Hyderabad-18 Telangana, India.

2. MSN Pharmaceuticals Inc. (“MSN Pharmaceuticals”) is a Delaware corporation having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

3. On information and belief, Exelixis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1851 Harbor Bay Parkway, Alameda, California 94502.

JURISDICTION AND VENUE

4. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over Exelixis because it is, on information and belief, a corporation organized and existing under the laws of the State of Delaware. This Court also has personal jurisdiction over Exelixis on the basis of, *inter alia*, its contacts with Delaware relating to the subject matter of this action, including having filed this suit.

6. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

7. Upon information and belief, Exelixis holds approved New Drug Application (“NDA”) No. 208692 for cabozantinib s-malate tablets, which Exelixis markets and sells, directly or indirectly, under the trade name CABOMETYX® in the United States, including this judicial district, in oral tablets having 20 mg, 40 mg, and 60 mg dosage strengths.

8. An NDA must include, among other things, the number of any patent that claims the “drug” or a “method of using [the] drug” for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

9. Upon approval of the NDA, the U.S. Food and Drug Administration (“FDA”) publishes patent information for the approved drug in the “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” *See* 21 U.S.C. § 355(j)(7)(A)(iii).

10. U.S. Patent. No. 7,579,473 (“’473 patent”), entitled “C-Met Modulators and Methods of Use,” was issued on August 25, 2009.

11. Upon information and belief, Exelixis is the assignee of the ’473 patent.

12. U.S. Patent. No. 8,497,284 (“’284 patent”), entitled “C-Met Modulators and Methods of Use”, was issued on July 30, 2013.

13. Upon information and belief, Exelixis is the assignee of the ’284 patent.

14. Upon information and belief, Exelixis caused the ’473 patent, the ’284 patent, U.S. Patent Nos. 8,877,776 (“the ’776 patent”), 9,724,342 (“the ’342 patent”), 10,034,873 (“the ’873 patent”) and 10,039,757 (“the ’757 patent”) to be listed in the Orange Book in connection with CABOMETYX®, a drug for which Exelixis submitted NDA No 208692.

15. U.S. Patent No. 9,809,549 (“the ’549 patent”), entitled “malate salt of N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)-N’-(4-fluorophenyl)-N’-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, and crystalline forms thereof for the treatment of cancer” (Exhibit A hereto), was issued by the United States Patent & Trademark Office on November 7, 2017.

16. On information and belief, Exelixis purports to be the owner of all right, title, and interest in the ’549 patent.

17. The ’549 patent contains 5 claims, of which claim 1 is independent. Claim 1 of the ’549 patent recites:

1. N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)-N’-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide (L) malate salt, wherein said salt is in crystalline Form N-1 and said Form N-1 is characterized by at least one of the following:

(i) a solid state ^{13}C NMR spectrum with four or more peaks selected from 18.1, 42.9, 44.5, 70.4, 123.2, 156.2, 170.8, 175.7, and 182.1, ± 0.2 ppm;

(ii) a powder x-ray diffraction pattern ($\text{CuK}\alpha$ $\lambda=1.5418$ Å) comprising four or more 2θ values selected from: $12.8\pm 0.2^\circ$ 2θ , $13.5\pm 0.2^\circ$ 2θ , $16.9\pm 0.2^\circ$ 2θ , $19.4\pm 0.2^\circ$ 2θ , $21.5\pm 0.2^\circ$ 2θ , $22.8\pm 0.2^\circ$ 2θ , $25.1\pm 0.2^\circ$ 2θ , $27.6\pm 0.2^\circ$ 2θ , wherein measurement of the crystalline form is at room temperature; and/or

(iii) an x-ray powder diffraction (XRPD) pattern substantially in accordance with the pattern shown in FIG. 1.

18. Claims 2-5 of the ’549 patent depend directly or indirectly from claim 1 and incorporate all elements of claim 1.

19. MSN submitted Abbreviated New Drug Application (“ANDA”) No. 213878 to obtain FDA approval to engage in the commercial manufacture, use, and sale of cabozantinib S-malate tablets, 20 mg, 40 mg, and 60 mg (“MSN’s ANDA Products”) prior to the expiration of the ’473 patent and ’284 patent, the ’776 patent, the ’342 patent, the ’873 patent, and the ’757 patent, as well as the ’549 patent.

20. MSN's ANDA No. 213878 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '473 patent, the '284 patent, the '776 patent, the '342 patent, and the '757 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of MSN's ANDA Products.

21. MSN's ANDA includes a statement, pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) and 21 C.F.R. § 314.94(a)(12)(iii)(A) ("Paragraph (viii) Statement"), that the '284 patent does not claim a use for which MSN is presently seeking approval expect for uses that are subject to MSN's Paragraph IV certification.

22. With respect to the '873 patent, MSN's ANDA includes a Paragraph (viii) Statement that the '873 patent does not claim a use for which MSN is presently seeking approval.

23. The MSN ANDA does not contain a certification under 21 U.S.C. § 505(j)(2)(A)(vii) with respect to the '549 patent because Exelixis has not caused the '549 patent to be listed in the Orange Book.

24. MSN provided notice of its certification with respect to *inter alia* the '776 patent to Exelixis, and that notice was received by Exelixis on or about September 24, 2019. The notice provided the factual and legal bases as to why, in MSN's opinion, the '776 patent is invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of MSN ANDA Products before the expiration of these patents. MSN also enclosed an Offer of Confidential Access to MSN's ANDA in accordance with 21 U.S.C. § 505(j)(5)(C)(i)(III) to allow Exelixis the opportunity to review the relevant portions of MSN's ANDA.

25. On October 29, 2019, Exelixis sued MSN alleging infringement of the '776 patent in the Civil Action No. 1:19-cv-2017-RGA in the District of Delaware (the "Exelixis 2019 Infringement Action").

26. By letter dated May 4, 2020 (the “Notice Letter”), pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, MSN notified Exelixis that ANDA No. 213878 includes Paragraph IV Certifications with respect to the ’473 patent and ’284 patent. MSN’s Notice Letter contained a detailed statement of the factual and legal bases for MSN’s Paragraph IV certification that the claims of the ’473 patent and the ’284 patent are invalid, unenforceable, and/or will not be infringed by MSN’s ANDA Products.

27. On May 11, 2020, Exelixis filed this instant lawsuit alleging infringement of the ’473 patent and ’284 patent (“Exelixis 2020 Infringement Action”).

28. By maintaining the Orange Book listing of the ’473 patent and the ’284 patent in connection with CABOMETYX®, Exelixis continues to represent that the ’473 patent and the ’284 patent could reasonably be asserted against anyone making, using, or selling a generic cabozantinib s-malate tablets without a license from Exelixis.

29. The Exelixis 2019 Infringement Action and the Exelixis 2020 Infringement Action have been consolidated into the Exelixis Consolidated Infringement Action.

30. As part of the Exelixis 2019 Infringement Action, Exelixis alleges *inter alia* that “[t]he ’776 patent claims crystalline Form N-2 of cabozantinib L-malate, compositions and methods using the same,” that “MSN’s submission of ANDA No. 213878 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Products before the expiration of the ’776 Patent constituted an act of infringement of at least claims 1-2 of the ’776 Patent, under 35 U.S.C. § 271(e)(2)(A),” and that “Upon FDA approval of ANDA No. 213878, MSN will infringe at least claims 1-2 of the ’776 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the MSN ANDA Products and/or its active ingredient, and/or by actively inducing and contributing to

infringement of the '776 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court.”

31. By April 30, 2020, as part of the Exelixis Consolidated Infringement Action, MSN produced to Exelixis’s counsel in that action a copy of MSN’s ANDA as well as the confidential Drug Master File submitted to the FDA concerning the active ingredient in the MSN ANDA Products. Exelixis’s outside counsel in the Exelixis Consolidated Infringement Action has had access to the MSN ANDA and the Drug Master File for purposes of assessing whether Exelixis believes MSN’s ANDA Product would infringe the '549 patent.

32. By July 31, 2020, MSN produced to Exelixis samples of the MSN ANDA Products, the active ingredient in the MSN ANDA Products, and all excipients in the MSN ANDA Products. Exelixis’s outside counsel in the Exelixis Consolidated Infringement Action has had access to samples of the MSN ANDA Products, the active ingredient in the MSN ANDA Products, and all excipients in the MSN ANDA Products for purposes of assessing whether Exelixis believes MSN’s ANDA Products would infringe the '549 patent.

33. The MSN ANDA Products, if marketed and sold in the United States prior to the expiration of the '549 patent, would not infringe any claim of the '549 patent at least because the MSN ANDA Products do not and will not contain any of the crystalline form of the compound required in claim 1 of the '549 patent and all of the other claims of the '549 patent (claims 2-5) that depend from claim 1.

34. On December 3, 2020, MSN asked Exelixis for a covenant not to sue as to the '549 patent on the basis that the MSN ANDA Products would not infringe any claim of the '549 patent if sold and marketed. On December 16, 2020, Exelixis declined MSN’s request and has not covenanted to MSN that it will not sue MSN for infringement of the '549 patent.

35. MSN has made, and will continue to make, substantial preparations in connection with its request for FDA approval of its ANDA Products.

36. Upon FDA approval of MSN's ANDA, MSN will be able to market and sell its ANDA Products in the United States.

37. Exelixis's conduct impairs MSN's ability to market MSN's ANDA Products. MSN thus seeks a declaratory judgment that its ANDA Products do not infringe the '473 patent and the '284 patent and/or that these patents are invalid and/or unenforceable.

38. Exelixis's conduct impairs MSN's ability to market the MSN ANDA Products because Exelixis still purports to maintain the right to sue MSN for infringement of the '549 patent if MSN gains FDA approval to market and sell the MSN ANDA Products. MSN thus seeks a declaratory judgment that the MSN ANDA Products do not infringe the '549 patent and/or this patent is invalid and/or unenforceable.

COUNT I
(Declaratory Judgment of Non-Infringement of the '473 Patent)

39. MSN re-alleges and incorporates by reference the allegations in paragraphs 1-38 of its Counterclaims.

40. Exelixis alleges ownership of the '473 patent, and Exelixis has brought claims against MSN alleging infringement of the '473 patent.

41. The manufacture, use, or sale of MSN's ANDA Products would not infringe any valid or enforceable claim of the '473 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

42. There is an actual, substantial, continuing and justiciable controversy between the parties regarding whether the filing of MSN's ANDA No. 213878 and/or the manufacture, use,

offer to sell, sale, and/or importation into the United States of MSN's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '473 patent.

43. MSN has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '473 patent and is not liable for such infringement.

44. MSN is entitled to a declaration that the manufacture, use, or sale of its ANDA Products would not infringe any valid or enforceable claim of the '473 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '473 Patent)

45. MSN re-alleges and incorporates by reference the allegations in paragraphs 1-38 of its Counterclaims.

46. Exelixis alleges ownership of the '473 patent, and Exelixis has brought claims against MSN alleging infringement of the '473 patent.

47. One or more claims of the '473 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112.

48. One or more claims of the '473 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in MSN's Notice Letter that Exelixis received.

49. The '473 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

50. The alleged invention of the '473 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '473 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been

motivated to combine the teachings of the prior art to achieve the alleged invention of the '473 patent and would have had a reasonable expectation of success in doing so.

51. The subject matter claimed in the '473 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

52. There is an actual, substantial, continuing and justiciable controversy between the parties regarding whether the filing of MSN's ANDA No. 213878 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of MSN's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '473 patent.

53. MSN is entitled to a declaration that all claims of the '473 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT III
(Declaratory Judgment of Non-Infringement of the '284 Patent)

54. MSN re-alleges and incorporates by reference the allegations in paragraphs 1-38 of its Counterclaims.

55. Exelixis alleges ownership of the '284 patent, and Exelixis has brought claims against MSN alleging infringement of the '284 patent.

56. The manufacture, use, or sale of the MSN ANDA Products would not infringe any valid or enforceable claim of the '284 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

57. There is an actual, substantial, continuing and justiciable controversy between the parties regarding whether the filing of MSN's ANDA No. 213878 and/or the manufacture, use,

offer to sell, sale, and/or importation into the United States of MSN's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '284 patent.

58. MSN has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '284 patent and is not liable for such infringement.

59. MSN is entitled to a declaration that the manufacture, use, or sale of its ANDA Products would not infringe any valid or enforceable claim of the '284 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '284 Patent)

60. MSN re-alleges and incorporates by reference the allegations in paragraphs 1-38 of its Counterclaims.

61. Exelixis alleges ownership of the '284 patent, and Exelixis has brought claims against MSN alleging infringement of the '284 patent.

62. One or more claims of the '284 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112.

63. One or more claims of the '284 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in MSN's Notice Letter that Exelixis received.

64. The '284 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

65. The alleged invention of the '284 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '284 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to

combine the teachings of the prior art to achieve the alleged invention of the '284 patent and would have had a reasonable expectation of success in doing so.

66. The subject matter claimed in the '284 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

67. There is an actual, substantial, continuing and justiciable controversy between the parties regarding whether the filing of MSN's ANDA No. 213878 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of MSN's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '284 patent.

68. MSN is entitled to a declaration that all claims of the '284 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT V
(Declaratory Judgment of Non-Infringement of the '549 Patent)

69. MSN re-alleges and incorporates by reference the allegations in paragraphs 1-38 of its Counterclaims.

70. Exelixis alleges ownership of the '549 patent, and Exelixis has declined MSN's request for a covenant not to sue MSN as to the '549 patent.

71. The manufacture, use, or sale of MSN's ANDA Products would not infringe any valid or enforceable claim of the '549 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

72. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of MSN's ANDA No. 213878 and/or the manufacture, use,

offer to sell, sale, and/or importation into the United States of the MSN ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '549 patent.

73. MSN has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '549 patent and is not liable for such infringement.

74. MSN is entitled to a declaration that the manufacture, use, or sale of MSN's ANDA Product would not infringe any valid or enforceable claim of the '549 patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '549 Patent)

75. MSN re-alleges and incorporates by reference the allegations in paragraphs 1-38 of its Counterclaims.

76. Exelixis alleges ownership of the '549 patent, and Exelixis has declined MSN's request for a covenant not to sue MSN as to the '549 patent.

77. One or more claims of the '549 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112.

78. For example, the specification of the '549 patent fails to sufficiently describe the subject matter recited in the claims and fails to show that the named inventors actually invented the claimed N-1 form of what the patent defines as Compound (I). Specifically, the specification does not show that the named inventors were in possession of the claimed N-1 form of Compound (I). Because the named inventors failed to convey with reasonable clarity to those skilled in the art, as of the filing date of the '549 patent, that the named inventors were in possession of the claimed invention(s) and demonstrate that by what is actually disclosed in the patent specification, one or more claims of the '549 patent are invalid under 35 U.S.C. § 112.

79. The '549 patent also fails to disclose sufficient information to enable or teach a person skilled in the art, at the time the patent application was filed, how to make and use the full scope of the pharmaceutical composition for modified release recited in the patent claims, without undue experimentation, because it would not teach a person skilled in the art how to make the N-1 form of what the patent defines as Compound (I), and therefore one or more claims of the '549 patent are invalid under 35 U.S.C. § 112.

80. The claims of the '549 patent, read in light of the corresponding specification and prosecution history, also fail to inform, with reasonable certainty, those skilled in the art of the full scope of the claims regarding the N-1 form of Compound (I), and therefore one or more claims of the '549 patent are invalid under 35 U.S.C. § 112.

81. Additionally, in the alternative, and to the extent Exelixis claims or it is found that Form N-1 of the cabozantinib malate salt is a more stable polymorphic form and that conversion from a less stable to a more stable form of cabozantinib malate is likely, then the claims of the '549 patent merely claim the more stable form of cabozantinib malate (N-1), which would have been obvious to a person of ordinary skill in the art under 35 U.S.C. § 103.

82. There is an actual, substantial, continuing and justiciable controversy between the parties regarding whether the filing of MSN's ANDA No. 213878 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of MSN's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '549 patent.

83. MSN is entitled to a declaration that all claims of the '549 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, MSN requests judgment in its favor and against Exelixis as follows:

- a. Declaring that all claims of the '473 patent, the '284 patent, and the '549 patent are invalid;
- b. Declaring that the filing of MSN's ANDA No. 213878 has not infringed and does not infringe any valid and enforceable claim of the '473 Patent, the '284 Patent, and the '549 Patent.
- c. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of MSN's ANDA Products does not, and would not, if marketed, infringe any valid and enforceable claim of the '473 patent, the '284 patent, and the '549 patent.
- d. Enjoining Exelixis and its agents, representatives, attorneys, and those persons in active concert or participation with it who receive actual notice hereof, from threatening or initiating infringement litigation against MSN or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of MSN, or charging it either orally or in writing with infringement of any patent asserted herein against MSN;
- e. Enjoining Exelixis and its agents, representatives, attorneys, and those persons in active concert or participation with it who receive actual notice hereof, from interfering with the FDA's approval of ANDA No. 213878;
- f. Declaring this an exceptional case in favor of MSN and awarding its attorneys' fees pursuant to 35 U.S.C. § 285.
- g. Awarding costs and expenses; and
- h. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: March 23, 2021

HEYMAN, ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
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